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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,086	06/22/2001	Charles J. Matson	53963USA1A	3790

32692 7590 10/22/2003

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EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	14

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,086	MATSON ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspond nc address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/03 has been entered.

Specification

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz (US 57501356), and further in view of Urry (US 5527610).

Scholz discloses a bioadhesive composition that adheres suitably to a mucosal surface and is capable of delivering drugs in sustained fashion. The bioadhesive composition comprises 1) a particulate polymeric resin with an average particle size of less than or equal to about 100 um and comprising at least about 55% by weight of carboxylic acid moieties based on the total of the polymeric resin; 2) from about 20 parts to about 250 parts by weight of a hydrophobic elastomeric component, based on 100 parts by weight of the resin and 3) an amount of a drug effective to provide a desired therapeutic results, wherein the resin and the drug are dispersed

substantially throughout the elastomeric component and adheres to a mucosal surface. In a preferred embodiment when systemic treatment is desired, the bioadhesive composition has a backing such as a flexible film applied to it. Further, in yet another preferred embodiment the resin is crosslinked (see col. 2). The polymeric resin component may be linear polyacrylic acid resins with a molecular weight between about 400,000 and about 500,000. More preferred, however, are crosslinked resins. Particularly preferred resins of this type include resins available under the trade designation CARBOPOL™ resin (see col. 3 lines 19-53). By itself, a polymeric resin as described above generally possesses insufficient structural integrity. Such acidic resins can also be irritating to mucosal tissue. Further, a resin alone provides no means of controlled hydration and sustained release of drug. To remedy these deficiencies, the resin is substantially dispersed throughout a hydrophobic elastomeric compound. Examples of materials suitable for use in an elastomeric component include: polyolefins such as polyisoburylenes, polybutadines, butyl rubber and isoprene rubber and mixtures and blends of two or more (see col. 4). Drugs that can be delivered include those useful for local treatment of the mouth or throat or vaginal cavity, in addition to those useful for systemic treatment via delivery through mucosal tissue. Practical limitations o the amount of drug incorporated in a composition are the amount above which the composition begins to lose adhesion to a mucosal surface. Generally, the preferred range is from about 0.1% to about 25% by weight based on the total weight of the bioadhesive composition (see cols. 6-7). Other ingredients, such as penetration enhancers, may also be added. Penetration enhancers have particular utility when used with drugs such as proteins or peptides. Specific penetration enhancers include glyceryl monolaurate (see col. 8, lines 5-21). Scholz does not

specifically disclose the butyl rubber to be cross-linked or the specific drugs medetomidine or dexmedetomidine.

Urry discloses a bioelastomer comprising tetrapepide and/or pentapeptide monomeric units of the formula I (see abstract). The bioelastomer can be uncrosslinked or crosslinked, depending on the manner of its ultimate use. For example, if the bioelastomer is used as a surface coating on a second material that provides appropriate mechanical properties, crosslinking is not necessary to proved mechanical strength. Cross-linking provides mechanical strength and rigidity to the polymer, and increasing amounts of cross-linking are appropriate for increasing demands of rigidity (see col. 5).

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the butyl rubber taught by Scholz by crosslinking the polymer to provide strength and rigidity to the polymer as taught by Urry. As for the specific pharmacological agents in claims 18 and 19, it is the position of the examiner it would be obvious to use any useful pharmacological agent, as indicated in both the instant application (see pages 9-11 of the specification) and in the above reference Scholz. Therefore, the examiner sees no criticality in the specific agents in claims 18 and 19.

Response to Arguments

4. Applicant's arguments filed 9/15/03 have been fully considered but they are not persuasive.

Applicants argue the prior art fails to teach or suggest all the claim limitations. Specifically, neither Scholz nor Urry teach or suggest a transmucosal drug delivery including an elastomeric polymer that is 30% - 80% crosslinked. The examiner refers to Urry wherein Urry

discloses cross-linking provides mechanical strength and rigidity to the polymer, and increasing amounts of cross-linking are appropriate for increasing demands of rigidity (see col. 5). Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the butyl rubber taught by Scholz by crosslinking the polymer to provide strength and rigidity to the polymer as taught by Urry. The % of the elastomeric polymer that would be crossed linked would depend on the desired rigidity as taught by Urry. It is the position of the examiner, one of ordinary skill in the art would determine a suitable % crosslinking depending on the intended use of the bioelastomer. Therefore, the % crosslinking is not found to be critical.

Applicants also argue Scholz does not identify rigidity demands as a concern or a limitation. Furthermore, Scholz teaches that the elastomeric components preferably are soft such that the ultimate composition can be worn without significant discomfort to the user. It is the position of the examiner, it is within the skill of the art, in view of both Scholz and Urry, to crosslink the elastomeric polymer to provide mechanical strength and rigidity. The percent crosslinked would depend on the ultimate use. Scholz prefers the elastomeric component be soft such that the ultimate composition can be worn without significant discomfort to the user and therefore one of ordinary skill in the art would determine the % crosslinked to achieve an elastomeric component which is soft such that the ultimate composition can be worn without significant discomfort to the user. Applicants themselves admit "reading Scholz and Urry together, one of orndinary skill in the art would have been motivated to provide a low degree of crosslinking in the elastomeric polymer – but not as much as 80% crosslinking – in order to

manufacture a soft, comfortable transmucosal drug delivery device" (see page 3 of Response filed 2/11/03). Claim 11 is not limited to 80% crosslinked.

Lastly, Applicants argue nothing in Scholz or Urry teaches or suggests improving bioadhesion through manipulating the extent of crosslinking in the elastomeric polymer. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., bioadhesion) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Therefore, the rejection is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600